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This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Rd., Building 100, Suite B; Durham, NC 27713; submitted 2/20/2005). This DER has been reviewed by the HED and revised to reflect current OPP policies.

STUDY REPORT:

45322107 Andersen, L., Walter, D., Spillner, C. (1998) Residue Levels in Potatoes Planted as a Rotational Crop Following Corn From Trials Carried Out in the United States of America During 1996: Lab Project Number: ACET-95-CR-01: RJ2543B. Unpublished study prepared by Zeneca Agrochemicals. 89 p.

EXECUTIVE SUMMARY:

Ten potato field rotational trials were conducted at field sites throughout the US during 1996. At each site, acetochlor (6.4 lb/gal EC) was applied to a primary crop of field or sweet corn as a preplant incorporated, at-planting, or preemergence broadcast application at 3.0 lb ai/A. The corn was grown and harvested following common agricultural practices. At each site, a rotational crop of potatoes was planted 291-377 days after treatment (DAT). Single control and duplicate treated samples of potatoes were harvested from each test at commercial maturity, 93-169 days after planting (419-530 DAT). Samples were stored frozen for up to 9 months prior to analysis, an interval supported by available storage stability data.

A GC/mass selective detector (MSD) method (RAM 280) was used to determine residues of acetochlor (converted to EMA) and its metabolites convertible to ethyl methyl aniline (EMA) and hydroxyethyl methyl aniline (HEMA) in potatoes. The LOQ is 0.01 ppm for both EMA and HEMA, or 0.02 ppm when expressed as acetochlor equivalents. The LOD was not reported. The extraction procedure in this method is substantially similar to the extraction scheme employed in the current enforcement method; therefore, HED concludes that this method has been adequately demonstrated to extract weathered residues and has been adequately validated for data collection purposes.

Following application of acetochlor (EC) to a primary crop of corn at 3.0 lb ai/A, residues of EMA and HEMA were each <LOQ (<0.02 ppm acetochlor equivalents) in all tuber samples for combined residues of <0.04 ppm expressed as acetochlor equivalents. No data were provided on residues of the hydroxymethyl ethyl aniline (HMEA) metabolites.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in this study, the field rotational crop data are classified as scientifically acceptable, although detailed soil information should be provided for applications made directly to the soil. The acceptability of this study for regulatory purposes is addressed in the forthcoming U. S. EPA document entitled *Acetochlor: Petitions for Tolerances on Sweet Corn and Rotational Crops of Nongrass Animal Feeds (Group 18), Sugar Beets, Dried Shelled Beans and Peas (Subgroup 6C), Sunflowers, Potatoes, Cereal Grains (Group 15), and Forage, Fodder, and Straw of Cereal Grains (Group 16). Summary of Analytical Chemistry and Residue Data* (D. Davis, D230310).

COMPLIANCE:

Signed and dated GLP, quality assurance, and data confidentiality statements were provided. No deviations from regulatory requirements were noted that would impact the study results or their interpretation.

A. BACKGROUND INFORMATION

Acetochlor is a chloroacetanilide herbicide used for preemergence control of weeds in corn. In the United States, acetochlor is conditionally registered for use on corn to the Acetochlor Registration Partnership (ARP), which is comprised of Monsanto and Dow AgroSciences. Acetochlor is formulated as a variety of emulsifiable concentrate (EC), emulsion in water (EW), microencapsulated (Mcap), or granular (G) formulations that can be applied to corn as a preplant, preemergence, or early postemergence application using only ground equipment. Tolerances are established for the combined residues of acetochlor and its metabolites convertible to EMA or HEMA, to be analyzed as acetochlor, and expressed as acetochlor equivalents [40 CFR §180.470]. Tolerances range from 0.05 to 1.5 ppm in/on corn commodities resulting from the direct use of acetochlor and from 0.02 to 1.0 ppm in commodities from rotational crops of sorghum, soybean, or wheat.

The ARP has submitted a petition (PP#1F6263) proposing tolerances for inadvertent residues of acetochlor in rotated dried peas and beans (subgroup 6C), sugar beets, sunflowers, potatoes, cereal grains (group 15, except corn and rice), and the forage, fodder, and straw of cereal grains (group 16, except corn and rice).

TABLE A.1. Acetochlor Nomenclature

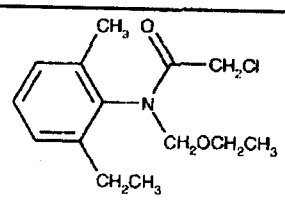
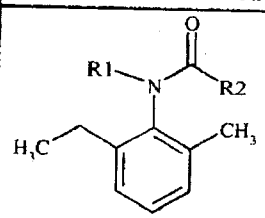
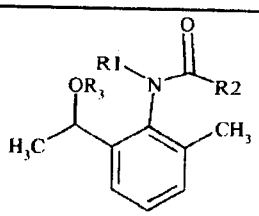
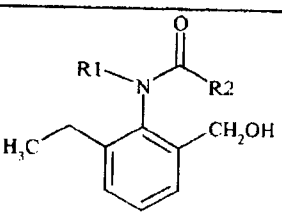
Chemical structure	
Common name	Acetochlor
Molecular Formula	$C_{14}H_{20}ClNO_2$
Molecular Weight	269.8
IUPAC name	2-chloro-N-ethoxymethyl-6'-ethylacet-o-toluidide
CAS name	2-chloro-N-(ethoxymethyl)-N-(2-ethyl-6-methylphenyl)acetamide
CAS #	34256-82-1
PC Code	121601
End-use Product	6.4 lb/gal EC

TABLE A.2. Physicochemical Properties of Acetochlor.

Parameter	Value	Reference
Boiling point/range	163 °C at 10 mm Hg; decomposition occurs before the boiling point at atmospheric pressure; (calculated by extrapolation of vapor pressure at lower temperature)	Acetochlor HED Chapter of the TRED, 3/1/06
pH	4.41, 1% solution in acetone:water (1:1, v:v)	
Density at 20 °C	1.123 g/mL	
Water solubility at 25 °C	223 mg/L	
Solvent solubility at 25 °C	Infinitely soluble in acetone, benzene, carbon tetrachloride, ethanol, chloroform, and toluene	
Vapor pressure at 25 °C	0.045 μ Hg (4.5×10^{-5} mm Hg)	
Dissociation constant, pK_a	Not applicable because acetochlor is neither an acid nor a base.	
Octanol/water partition coefficient	970 or 1082	
UV/visible absorption spectrum	Not available	

Table A.3. Acetochlor Metabolite Structures

Metabolite Type	Structure
EMA-type metabolites	
HEMA-type metabolites	
HMEA-type metabolites	

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

Ten field rotational crop trials were conducted at field sites throughout the U.S. during 1996 (Table B.1.1). At each test site, corn (sweet or field) was planted and treated once with acetochlor (6.4 lb/gal EC) at a target rate of 3 lb ai/A (1x maximum seasonal rate) using ground equipment (Table B.1.2). At each site, a rotational crop of potatoes was planted 291-377 days (10-12 months) after treatment. Two additional field trials were conducted in Regions 1 and 5. However, the wrong test material was used in these trials; therefore, the tests were discontinued. The study authors indicated that these trials would be repeated in a separate study.

Detailed soil characteristics and meteorological data were not provided for all sites, but maintenance pesticides and detailed plot history were provided. A general summary of the overall weather conditions was provided noting that usual weather conditions occurred at three of the sites. However, the weather conditions had no adverse impact to the residue data. Rainfall was supplemented with irrigation as needed.

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State, Year)	Soil characteristics			
	Type	%OM	pH	CEC (meq/g)
Lyons, NY 1996	Sandy Loam	4	5.9	NR
Whitakers, NC 1996	Sandy Loam	NR	NR	NR
Goldsboro, NC 1996	Sandy Loam	1.6	5.8	NR
Delavan, WI 1996	Silt Loam	NR	NR	NR
Cory, CO 1996	Clay Loam	NR	NR	NR
Visalia, CA 1996	Sandy Loam	NR	NR	NR
Minidoka, ID 1996	Silt Loam	NR	NR	NR
Jerome, ID 1996	Loam	NR	NR	NR
Hermiston, OR 1996	Sandy Loam	NR	NR	NR
Ephrata, WA 1996	Sandy Loam	NR	NR	NR

NR = Not reported

TABLE B.1.2. Study Use Pattern to Primary Corn Crop.

Location (County, State) Year	End-use Product	Application				Rotational Crop
		Method [1]; Timing	Vol. (GPA)	Application Rate (lb ai/A) [2]	PBI [3] (days)	
Lyons, NY 1996	6.4 lb/gal EC	Broadcast Soil: at-planting	18	3	352	Potatoes
Whitakers, NC 1996	6.4 lb/gal EC	Broadcast Soil: at-planting	30	3	334	Potatoes
Goldsboro, NC 1996	6.4 lb/gal EC	Broadcast Soil: preemergence	20	3	291	Potatoes
Delavan, WI 1996	6.4 lb/gal EC	Broadcast Soil: preemergence	25	3	358	Potatoes
Cory, CO 1996	6.4 lb/gal EC	Broadcast Soil: pre-planting	13	3	371	Potatoes
Visalia, CA 1996	6.4 lb/gal EC	Broadcast Soil: preemergence	15	3	300	Potatoes
Minidoka, ID 1996	6.4 lb/gal EC	Broadcast Soil: preemergence	21	3	329	Potatoes
Jerome, ID 1996	6.4 lb/gal EC	Broadcast Soil: preemergence	20	3	341	Potatoes
Hermiston, OR 1996	6.4 lb/gal EC	Broadcast Soil: pre-planting	19	3	361	Potatoes
Ephrata, WA 1996	6.4 lb/gal EC	Broadcast Soil: at-planting	18	3	377	Potatoes

1 All applications were made using ground equipment.
2 Actual application rates were not reported, but application rates were ± 10% of target.
3 Plant-back Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones[1]	Potatoes		
	Submitted	Requested	
		Canada	US
1	1	NA	2
2	2	NA	1
3	--	NA	1
4	--	NA	--
5	1	NA	2
6	--	NA	--
7	--	NA	--
8	--	NA	--
9	1	NA	1
10	1	NA	1
11	4	NA	4
12	--	NA	--
Total	10	NA	12

[1] Regions 13-21 and 1A, 5A, 5B, and 7A were not included as the use is restricted to the US.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of tubers (≥24 tubers) were harvested at commercial maturity 93-169 days after planting (414-530 DAT) from each test site. After collection, samples were placed in frozen storage at the test facility within 6 hours of collection, stored at the Western Research Center, CA and then shipped frozen to the analytical laboratory, Jealott's Hill Research Station, Berkshire, UK and stored frozen (~ -18 °C) prior to analysis. Samples were stored frozen for up to 9 months prior to EMA/HEMA analysis.

B.3. Analytical Methodology

Samples of potato tubers were analyzed for residues of acetochlor (converted to EMA) and its metabolites convertible to ethyl methyl aniline (EMA) and hydroxylethyl methyl aniline (HEMA)using GC/MSD Method RAM 280 (D. Davis, 44107103.der). For Method RAM280, residues are extracted with acetonitrile:water (80:20, v/v), concentrated, and base hydrolyzed by refluxing with saturated potassium hydroxide and methanol to yield EMA and HEMA. The resulting hydrolysate is diluted with water and saturated sodium chloride, and residues of EMA and HEMA are partitioned into toluene. Residues are acylated with heptafluorobutryic acid anhydride, and partitioned against a sodium bicarbonate solution to remove the derivatizing agent. Residues are then analyzed by GC/MSD operating in the selective ion monitoring (SIM) mode, and using the 162 and 314 ions for quantifying EMA and HEMA, respectively. Residues are quantified by comparison to external standards. The LOQ is 0.01 ppm for both EMA and HEMA, or 0.02 ppm when expressed as acetochlor equivalents. The LOD was not reported.

Method RAM 280 employs an extraction scheme substantially similar to that used in the current enforcement method; therefore, HED considers that this method is adequate to recover weathered

residues from field samples. Additionally, the method has been adequately validated as a data collection method based on the results of concurrent fortification sample spiked with HEMA- or EMA-type compounds.

In addition samples of potato tubers were analyzed for residues of acetochlor *per* se using a GC/NPD Method RAM 244/02 (D. Davis, 44107102.der). The registrant has not demonstrated that this method can extract field weathered residues; therefore data on residues of acetochlor *per se* from field samples are not considered supported by adequate validation data and are; therefore, not appropriate for use in risk assessment or for tolerance setting purposes. Further, since this data generated from analytical method RAM 244/02 is not of utility for regulatory purposes, it is not included in this document.

C. RESULTS AND DISCUSSION

Samples were stored frozen for a maximum of 9 months (Table C.1). Adequate storage stability data are available (D. Davis, 45483301.der) indicating that acetochlor and metabolites of EMA and HEMA are stable up to 9 months in potato. These data will support the frozen storage intervals in this trial.

The method used to determine the combined residues of acetochlor (converted to EMA) and its EMA- and HEMA-type metabolites in potatoes was adequately validated in conjunction with the field sample analyses (Table C.2).). Method validation and concurrent recovery samples fortified with EMA and HEMA yielded recoveries within the 70% to 120% acceptable range. Adequate samples calculations were provided along with example chromatograms. Apparent residues of both analytes were <LOQ in all control samples.

Residues of EMA and HEMA were <LOQ (<0.02 ppm acetochlor equivalents) in all tuber samples, for combined residues of <0.04 ppm. As the GC/MSD method would result in the conversion of acetochlor to EMA, combined residues are the sum of EMA and HEMA residues, expressed in acetochlor equivalents.

No data were provided for HMEA-type metabolites. Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Storage Conditions

Matrix	Analyte	Storage Temp. (°C)	Actual Storage Duration (months) [1]	Limit of Demonstrated Storage Stability (months) [2]
Potatoes	EMA/HEMA	-18	9	9

[1] Samples extracts were analyzed within 4 days of extraction.
[2] D.Davis, 45483301.der

TABLE C.2. Summary of Method Recoveries of HEMA and EMA from Potato Tubers.

Matrix	Analytes [1]	Spike level (mg/kg)	Sample size (n)	Recoveries (%)	Mean ± std dev
Method Validation[2]					
Potato	EMA	0.01	4	96, 92, 91, 90	92 ± 2.6
		0.10	4	103, 101, 105, 101	102 ± 1.9
	HEMA	0.01	4	103, 101, 95, 104	101 ± 4.0
		0.10	4	89, 86, 90, 87	88 ± 1.8
Concurrent Recovery[3]					
Potato	EMA	0.02	4	77, 91, 88, 92	87 ± 6.9
		0.10	4	86, 89, 90, 95	90 ± 3.7
	HEMA	0.02	4	83, 91, 93, 89	89 ± 4.3
		0.10	4	89, 88, 93, 93	91 ± 2.6

[1] Residues containing the EMA or HEMA moieties were determined using GC/MSD Method RAM 280/02.
[2] Concentrations are residues of EMA/HEMA.
[3] Concentrations are expressed as acetochlor equivalents.

TABLE C.3. Residues of Acetochlor, EMA and HEMA in Rotational Potatoes.

Location (County, State, Year)	EPA Region	Variety	Total Rate (lb ai/A)	PBI [1] (days)	Harvest DALA[2]	Residues (ppm) [3]		
						EMA	HEMA	Combined [4] Residues
Lyons, NY 1996 57-NY-96-402	1	Chieftan	3	352	452	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Whitakers, NC 1996 01-NC-96-403	2	Red Pontiac	3	334	427	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Goldsboro, NC 1996 47-NC-96-404	2	Kennebec	3	291	414	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Delavan, WI 1996 79-WI-96-406	5	Superior	3	358	448	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Cory, CO 1996 14-CO-96-407	9	Centennial	3	371	524	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Visalia, CA 1996 02-CA-96-408	10	Chipper FL 1625	3	300	419	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Minidoka, ID 1996 16-ID-96-409	11	Russet Burbank	3	329	462	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Jerome, ID 1996 16-ID-96-410	11	Russet Burbank	3	341	468	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Hermiston, OR 1996 16-OR-96-411	11	Russet Burbank	3	361	530	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04

TABLE C.3. Residues of Acetochlor, EMA and HEMA in Rotational Potatoes.

Location (County, State, Year)	EPA Region	Variety	Total Rate (lb ai/A)	PBI [1] (days)	Harvest DALA[2]	Residues (ppm) [3]		
						EMA	HEMA	Combined [4] Residues
Ephrata, WA 1996 15-WA-96-412	11	Russet Burbank	3	377	509	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04

1 PBI = Plant Back Interval.
2 DALA= Days after last application.
3 The LOQ is 0.02 ppm for EMA and HEMA. The LOD was not reported
4 As acetochlor is converted to EMA by the GC/MSD method, the combined total residues are the sum of EMA and HEMA residues, expressed in acetochlor equivalents.

TABLE C.4. Summary of Residue Data in Rotational Potatoes

Commodity	Total Rate (lb ai/A)	PBI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT[2]	Median (STMdR[3])	Mean (STMR[3])	Std. Dev.
EMA									
Potato	3.0	291-377	20	<0.02	<0.02	<0.02	0.01	0.01	NA
HEMA									
Potato	3.0	291-377	20	<0.02	<0.02	<0.02	0.01	0.01	NA
Combined Residues [4]									
Potato	3.0	291-377	20	<0.04	<0.04	<0.04	0.02	0.02	NA

1 LOQ is 0.02 ppm for EMA and HEMA. The LOD was not reported.
2 HAFT = Highest Average Field Trial.
3 STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue. For calculation of the median, mean and standard deviation, ½ the LOQ (0.005 or 0.01 ppm) was used for residues reported at <LOQ.
4 As acetochlor is converted to EMA by the GC/MSD method, the combined total residues are the sum of EMA and HEMA residues, expressed in acetochlor equivalents.

D. CONCLUSION

HED concludes that the submitted study is adequately supported by field documentation and storage stability data and was derived using a validated analytical method.

In ten field trials conducted at various locations throughout the U.S. potatoes were planted 10 – 12 months following application of acetochlor to a primary crop of corn at 3.0 lb ai/A. In all tuber samples residues of EMA and HEMA were each <LOQ (<0.02 ppm acetochlor equivalents) for combined residues of <0.04 ppm expressed as acetochlor equivalents. No data were provided on residues of the hydroxymethyl ethyl aniline (HMEA) metabolites.

E. REFERENCES

DP Barcode: D292336
Subject: **ACETOCHLOR**. Revised HED Chapter of the Tolerance Reassessment Eligibility Decision (TRED) Document.
From: A. Protzel
To: F. Fort
Dated: 3/1/06
MRID(s): None

F. DOCUMENT TRACKING

RDI: D. Davis (3/23/06), M. Doherty (4/17/06).
Petition Number(s): 1F6263
DP Barcodes: D230310 and D275019
PC Code: 121601